IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 8932-802-999

Group Art Unit:	3733	
Examiner:	Woodall, Nicholas W.	
Inventor:	Hehli et al.	**PRE-APPEAL BRIEF CONFERENCE REQUEST**
Serial No.:	10/694,846	
Filed:	October 29, 2003	
For:	OSTEOSYNTHETIC DEVICE	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant hereby requests review of the Final Rejection mailed April 4, 2007 ("Final Rejection") of the above-captioned application prior to filing an appeal brief for the reasons set forth below. Applicant submits that the Final Rejection fails to establish a *prima facie* rejection.

I. PROSECUTION SUMMARY

Claims 1, 2, 7, 9, 13, 14, and 17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,626,613 to Schmieding ("Schmieding"). Claims 3-6, 8, 10-12, 15-16, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schmieding.

Independent claim 1 recites "[a]n osteosynthetic device comprising an *intramedullary nail*."[1] An "intramedullary nail" is a device to be inserted into an intramedullary canal to,

[1] All emphasis added unless otherwise noted.

inter alia, provide support to fractures of long bones. (*See* paragraphs [0002]-[0006], [0008], [0010] of the present application).

Schmieding describes a corkscrew suture anchor 2 for reattaching soft tissue to bone. (*See, e.g., id.* at 1:7-16, Figure 1). The suture anchor 2 has a sharp point 10 adapted to pierce bone and form a tunnel within bone, and a suture eye 8 for receiving a suture. (*See id.* 3:18-24, 3:61-63, Figure 1). There is absolutely no disclosure in Schmieding of inserting the suture anchor 2 in an intramedullary canal, nor is there disclosure of providing support of a long bone with the suture anchor 2.

The Examiner first asserted Schmieding in the Non-Final Office Action dated September 1, 2006 ("Non-Final Action"), whereby the Examiner merely referred to Schmieding as a "device." (*Id.* at 11). In response, and in an attempt to clarify that "intramedullary nail" was intended to be a limitation of independent claim 1, Applicants amended claim 1 to place the claim recitation "intramedullary nail" in the body of claim 1. (Amendment under 37 C.F.R. § 1.111 dated December 28, 2006 at 4). Applicants further argued that Schmieding does not disclose an "intramedullary nail." (*Id.* at 7-8).

The Examiner thereafter submitted the Final Rejection, which incorrectly treated "intramedullary nail" as a "statement[] of intended use [or] functional statement," and moreover remarked that "[t]he examiner believes the device of Schmieding is capable of being used as an intramedullary nail in the bone of an organaism [*sic*] smaller than a human." (Final Rejection at 4-5). In response, Applicants submitted an Amendment under 37 C.F.R. § 1.116 dated May 29, 2007, which again pointed out Schmieding's failure to describe an "intramedullary nail," and provided a detailed rebuttal to the Examiner's arguments.

The Examiner finally submitted an Advisory Action dated June 13, 2007 ("Advisory Action"), which maintained the claim rejections, and asserted that "[t]he applicant's [*sic*] argument that 'intramedullary nail' is a structural limitation is not persuasive." (*Id.* at 2). The Examiner further stated: "The term 'intramedullary' is a functional adjective added to

the noun nail, which recites that the nail is capable of being placed in the intramedullary canal of a bone. The device of Schmieding is capable of being used as an intramedullary nail is one so desired." (*Id.*).

II. FAILURE TO ESTABLISH A *PRIMA FACIE* CASE OF ANTICIPATION

A *prima facie* case of anticipation has not been made with regard to independent claim 1, and its dependent claims 2, 7, 9, 13, 14, and 17, because Schmieding fails to disclose each and every element of claim 1.

Schmieding does not anticipate claim 1 because Schmieding fails to disclose an "intramedullary nail." Instead, Schmieding discloses a corkscrew suture anchor, which fails to describe the structural limitation of "intramedullary nail." The Schmieding suture anchor secures soft tissue to bone and is adapted to form a helical tunnel in the bone. (*Id.* at 3:61-4:8). As previously stated, Schmieding does not disclose a device to be inserted into the intramedullary canal to, *inter alia*, provide support to fractures of long bones. (*See* paragraphs [0002]-[0006], [0008], [0010] of the present application). Although it is not required that the reference "teach" what the subject patent teaches, claim 1 simply does not "read on" anything in Schmieding, since Schmieding does not describe all the limitations of claim 1. *Kalman v. Kimberly-Clark Corp.*, 218 U.S.P.Q. 781, 786 (C.C.P.A. 1983).

Examiner also separates the term "intramedullary nail" into two parts, stating that "[t]he term 'intramedullary' is a functional adjective" modifying the term "nail." (Advisory Action at 2). This argument ultimately fails for several reasons. First, Applicants respectfully submit that the term "intramedullary nail" is instead recognized by those of skill in the art as a single term, which is structurally distinct from the Schmieding corkscrew suture anchor. The present application clearly utilizes to "intramedullary nail" as a single term. (*See, e.g.*, [0002], [0003], [0005], [0007], [0009], [0010] of the present application). Second, even if the term "intramedullary" is an adjective, that alone is not a sufficient reason to unilaterally read it out of the claim. For example, using the Examiner's erroneous

reasoning in light of Schmieding, one should read out the term "suture" from "suture anchor" in claim 1, thus embracing ship anchors as prior art. Third, even accepting the Examiner's argument that the term "intramedullary nail" is separable, and reading the "functional adjective" out of the claim, Examiner's argument still fails because a "nail" is structurally distinct from a corkscrew.[2]

Examiner's belief that the Schmieding suture anchor "is capable of being used as an intramedullary nail if one so desired" is unfounded and irrelevant. (Advisory Action at 2). As stated previously, there is absolutely no disclosure that the suture anchor 2 of Schmieding can be inserted into an intramedullary canal to, *inter alia*, provide support to fractures of long bones. (A corkscrew suture anchor is not an intramedullary nail). Even if such a use were possible, a device does not anticipate merely because it is capable of performing the same function as the patented device. *See* MPEP § 2114. Creative uses for the prior art are irrelevant where it is structurally distinct from the Applicants' invention. *See id.* Numerous issues would arise using the corkscrew suture anchor in the intramedullary canal of a long bone — for example, where would the bulbous portion having the suture eye 8 be situated after implantation? The Examiner gives no discussion to these, and other, considerations.

Examiner's prior citation of caselaw is similarly irrelevant. *In re Casey*, 152 U.S.P.Q. 235 (C.C.P.A. 1967) and *In re Otto*, 136 U.S.P.Q. 458 (C.C.P.A. 1963) were cited for the proposition that statements of intended use and functional statements do not impose structural limitations on the claims. (Final Rejection at 4). These arguments fail because the term "intramedullary nail" is not a functional limitation, but instead is a structural limitation defining in part the osteosynthetic device of claim 1. *Casey* and *Otto* are further irrelevant because the cases relate to rejections for obviousness under 35 U.S.C. § 103, and Examiner is currently asserting that the claim 1 is anticipated by Schmieding. Examiner also cites *Ex parte Masham*, 2 U.S.P.Q. 2d 1647 (Bd. Pat. App. & Int. 1987) regarding statements of

[2] Applicants respectfully submit that technical knowledge is not required to differentiate a corkscrew from a nail, even a helical nail.

intended use. (Final Rejection at 5). This argument is similarly irrelevant, since Applicants' invention is not only different in intended use, but also in structure. Simply put, Schmieding's corkscrew suture anchor is not an "intramedullary nail," nor any sort of nail, and so cannot fully meet the limitations of claim 1. A reference that does not fully meet the limitations of a claim does not anticipate that claim, so Schmieding cannot anticipate claim 1. *See Kalman*, 218 U.S.P.Q. at 786.

The Examiner has not made a *prima facie* case of anticipation of independent claim 1, and therefore the rejection of claim 1, along with the rejections of dependent claims 2, 7, 9, 13, 14, and 17, should be withdrawn.

III. FAILURE TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS

Claims 3-6, 8, 10-12, 15-16, and 18 were rejected under 103(a) as being unpatentable over Schmieding. Independent claim 1 is not obvious in light of Schmieding because Schmieding does not teach, suggest, or describe an intramedullary nail, as discussed above. As claims 3-6, 8, 10-12, 15-16, and 18 depend on claim 1, the Applicants respectfully submit that the rejections of these claims should be withdrawn.

Respectfully submitted,

Date: August 2, 2007

s/ Brent P. Ray 54,390

Brent P. Ray (Reg. No.)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
8932-802-999	

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/694,846	10/29/03

First Named Inventor: Hebli et al.

Art Unit	Examiner
3733	Woodall, Nicholas W.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 54,390

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

Brent P. Ray
Typed or printed name

312-269-1521
Telephone number

8/2/07
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.